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10/510,276	08/22/2005	Robyn O'Hehir	JKJ-003US	9537

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/510,276	O'HEHIR ET AL.	
	Examiner	Art Unit	
	NORA M. ROONEY	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-9,11-40 and 45-52* is/are pending in the application.

4a) Of the above claim(s) *1,4-9,11-18,20-26,28-33,35,38-40,46,47 and 49-52* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2, 19, 27, 34, 36-37, 45, 48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 October 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *01/04/2007, 06/14/2007 and 05/19/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-2, 4-9, 11-40 and 45-52 are pending.

2. It is noted that in the restriction requirement mailed on 09/22/2008: Claims 36-37, 45 and 48 were improperly put into two different Groups (Groups I-II); Claims 38, 50 and 52 were improperly put into 2 different Groups (Groups III-IV); Claims 39-40 were improperly put into 4 different Groups (Groups V-VI and IX-X); and Claims 46-47 were improperly put into 2 different Groups (Groups VII-VIII). According to MPEP 814: "While every claim should be accounted for, the omission to group a claim, or placing a claim in the wrong group will not affect the propriety of a final requirement where the requirement is otherwise proper and the correct disposition of the omitted or erroneously grouped claim is clear."

3. The following represents the proper restriction of the claims required under 35 U.S.C. 121 and 372:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Group I, Claims 1-2, 4-9, 11-37, 45 and 48, drawn to an isolated Lol p 1 or Lol p 5 peptide, a pharmaceutical composition and a kit thereof.

Group II, Claims 38, 50 and 52, drawn to an isolated nucleic acid encoding an isolated Lol p 1 or Lol p 5 peptide.

Group III, Claims 39-40, drawn to a method for the treatment or prophylaxis of a condition in a subject, which condition is characterized by an aberrant, unwanted or otherwise inappropriate immune response to Lol p 1 and/or Lol p 5, comprising administering to said subject an effective amount of an Lol p 1 or Lol p 5 peptide.

Group IV, Claims 46-47, drawn to a method of diagnosing or monitoring a condition in a mammal, which condition is characterized by an aberrant, unwanted or inappropriate response to Lol p 1 and/or Lol p 5, said method comprising screening for Lol p 1 and/or Lol p 5 reactive T cells and/or antibodies utilizing an isolated Lol p 1 or Lol p 5 peptide.

Group V, Claim 49, drawn to a method for the treatment and/or prophylaxis of a condition in a subject, which condition is characterized by an aberrant, unwanted or otherwise inappropriate immune response to Lol p 1 and/or Lol p 5, said method comprising administering to said subject an effective amount of a nucleic acid encoding an Lol p 1 or Lol p 5 peptide.

Group VI, Claim 51, drawn to a method of diagnosing or monitoring a condition in a mammal, which condition is characterized by an aberrant, unwanted or inappropriate response to Lol p 1 and/or Lol p 5, said method comprising screening for Lol p 1 and/or Lol p 5 reactive T cells and/or antibodies utilizing a nucleic acid encoding an Lol p 1 or Lol p 5 peptide.

4. The following represents the proper species requirement under 35 U.S.C. 121:

If Group I, III or IV is elected, Applicant is further required to elect:

a single specific Lol p 1 or Lol p 5 peptide having a single specific amino acid sequence; and

If Group II, V or VI is elected, Applicant is further required to elect:

a single specific nucleic acid encoding a Lol p 1 or Lol p 5 peptide;

5. Applicant's election without traverse of Group II, claims 2, 11-16, 19-20, 23-28, 31-37, 45 and 48, drawn to an isolated Lol p 5 peptide and a pharmaceutical composition and kit thereof; and the Lol p 5 species of SEQ ID NO:53 in the reply filed on 11/19/2008 is acknowledged. Elected Group II and the Lol p 5 species of SEQ ID NO:53 of the restriction requirement mailed on 09/22/2008 corresponds to Group I set forth *supra*.

6. Claims 1, 4-9, 11-18, 20-26, 28-33, 35, 38-40 and 46-47 and 49-52 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Groups and species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/19/2008.

7. Claims 2, 19, 27, 34, 36-37, 45 and 48 are currently pending and under consideration as

they read on an isolated Lol p 5 peptide of SEQ ID NO:53, and a pharmaceutical composition or kit thereof.

8. Applicant's IDS documents filed on 01/04/2007, 06/14/2007 and 05/19/2008 are acknowledged.

Specification

9. The disclosure is objected to because of the following informalities:

The specification (including the abstract and claims), and any amendments for applications, except as provided for in 37 CFR 1.821 through 1.825, must have text written plainly and legibly either by a typewriter or machine printer in a nonscript type font (e.g., Arial, Times Roman, or Courier, preferably a font size of 12) lettering style having capital letters which should be at least 0.3175 cm. (0.125 inch) high, but may be no smaller than 0.21 cm. (0.08 inch) high (e.g., a font size of 6) in portrait orientation and presented in a form having sufficient clarity and contrast between the paper and the writing thereon to permit the direct reproduction of readily legible copies in any number by use of photographic, electrostatic, photo-offset, and microfilming processes and electronic capture by use of digital imaging and optical character recognition; and only a single column of text. See 37 CFR 1.52(a) and (b).

The application papers are objected to because Tables 3-5 on pages 61-63 of the specification are not legible.

A legible substitute specification in compliance with 37 CFR 1.52(a) and (b) and 1.125 is required.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 2, 19, 27, 34, 36-37, 45 and 48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claim 2 recites the limitation "X_2" in line 13. The recitation of "X_2" is indefinite as there is insufficient antecedent basis for this limitation in the claim, so it is unclear what Applicant intends by the recitation. It appears to the Examiner that X_2 in line 13 was inadvertently left in the claim in the amendment filed on 10/04/2004, wherein the other recitations of X_2 in the claim were deleted. Correction is required.

B. Claims 2 and 27 recite specific peptides by amino acid numbers without reference to a specified sequence identification number, which makes the claims indefinite. The recitation of amino acid positions without a reference sequence to which it refers is indefinite because amino acid position numbers depend on the proximity of the amino acids to the N-terminus of the sequence. For example, a Lol p 5 polypeptide with a leader sequence or N-terminal truncation

will have different amino acids at specific position numbers compared to a Lol p 5 polypeptide without a leader sequence or truncation. In the instant case, the claim are especially indefinite given that peptides may be derived from Lol p 5 homologs which may have little to no amino acid position number correspondence to native Lol p 5. Therefore, the amino acid identity of the peptides of Lol p 5 that Applicant intends to include in the instant claims is indefinite. Correction is required.

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 2, 19, 27, 34, 36-37, 45 and 48 *are* rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for: an Lol p 5 peptide consisting at least 5 contiguous amino acids of SEQ ID NOs 2 or 59-61 and the isolated peptides comprising an Lol p 5 T cell epitope of SEQ ID NOs 33-36, 42, 45-46, 48 and 51-54; the specification does not provide reasonable enablement for: an isolated peptide **comprising a Lol p 5 T cell epitope said peptide comprising at least 5 contiguous amino acids** of an amino acid sequence **derived** or selected from the group consisting of: (i) **amino acids 37-81**; (ii) **amino acids 118-137**; (iii) **amino acids 145-173:** (iv) **amino acids 172-191**; and (v) **amino acids 190-245**; inclusive of **Lol p 5 or a homolog thereof**; and wherein said peptide molecule is capable of **interacting with T cells** and **modifying T cell function** when incubated with cells from subjects having a condition

characterized by **an aberrant, unwanted or otherwise inappropriate immune response** to **Lol p 5 or a functional derivative, homologue, mutant or analogue** of said peptide provided that **X2** is not the amino acid sequence **100-119 or 190-209** of claim 2; wherein said amino acid sequence **comprises at least 5 amino acids derived** from amino acid sequences selected from the group consisting of: DVNAGFKAAVAAAANAPPAD (SEQ ID NO:33); ELQIVDKIDAAFKIAATAA (SEQ ID NO:45); DAAFKIAATAANAAPTNDKE (SEQ ID NO:46); PEVKYAVFEAALTKAITAMT (SEQ ID NO:53); and AALTKAITAMTQAQKAGKPA (SEQ ID NO:54) of claim 19; wherein said amino acid sequence is **amino acids 217-236** inclusive of **Lol p 5 or a homolog thereof** of claim 27; wherein said amino acid sequence **corresponds substantially to SEQ ID NO:53** of claim 34; wherein said **modification of T cell functioning** is the induction of T cell differentiation of claim 36; wherein said **peptide** exhibits reduced or ablated IgE binding of claim 37; a **pharmaceutical composition** comprising a peptide according to claim 1 or 2 together with one or more pharmaceutically acceptable carriers and/or diluents of claim 45; and a diagnostic kit for use in **diagnosing or monitoring a condition** in **a mammal**, which **condition is characterized by an aberrant, unwanted or inappropriate response to Lol p 1 and/or Lol p 5**,wherein said kit comprises **a peptide** according to claim 2 of claim 48. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with this claim.

The specification disclosure does not enable one skilled in the art to practice the invention without an undue amount of experimentation.

Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the lack of sufficient working examples, the unpredictability in the art and the amount of experimentation required to enable one of skill in the art to practice the claimed invention.

The specification discloses the amino acid sequences of Lol p 5 (SEQ ID NO:2); three isoforms of Lol p 5: Lol p 5A (SEQ ID NO: 59), Lol p 5C (SEQ ID NO:60) and Lol p 5B (SEQ ID NO:61); and SEQ ID NOs 33-36, 42, 45-46, 48 and 51-54 (In particular, Figures 3-4, whole document).

The specification does not adequately disclose the genus of isolated peptides "comprising" a Lol p 5 T cell epitope for use in the claimed invention. The term "comprising" is open language which opens up the recited peptides to read on any peptide comprising a Lol p 5 T cell epitope and having any number of undisclosed amino acid residues added onto the N- and/or C-terminus of the Lol p 5 T cell epitope. The specification has not provided adequate guidance to determine which peptides of the genus of recited peptides may be used for the claimed function of interacting with T cells and modifying T cell function when incubated with cells from subjects having a condition characterized by an aberrant, unwanted or otherwise inappropriate immune response to Lol p 5. The recited peptides read on peptides whose function

may be attributed to the undisclosed portions and not to Lol p 5 T cell epitopes at all. The specification has also not disclosed the genus of isolated peptides comprising a Lol p 5 T cell epitope comprising 5 or more amino acids of an amino acid sequence "derived" from a Lol p 5 amino acid sequence. The term "derived" encompasses sequences having any number of additions, deletions and substitutions, so long as the sequence is a derivative of at least a subsequence of Lol p 5. Skolnick et al. (PTO-892, Reference U) teaches that sequence-based methods for function prediction are inadequate and knowing a protein's structure, i.e., amino acid sequence, does not necessary tell one its function (In particular, abstract, entire document). Attwood et al. (PTO-892, Reference V) teaches that protein function is context-dependent and the state of the art of making functional assignments merely on the basis of some degree of similarity between sequences and the current structure prediction methods is unreliable (In particular, entire document). Determining which peptides of the genus of peptides encompassed by the instant claim recitations that would exhibit the requisite function would be unpredictable. Without adequate guidance in the specification, one of ordinary skill in the art would be required to perform undue experimentation to practice the claimed invention commensurate in scope with the claims.

The specification has not adequately disclosed limiting definitions for the terms "interacting with T cells" and "modifying T cell function" such that one of ordinary skill in the art would be able to determine which of the recited peptides exhibited these requisite functions. The term "interacting" is not limited to specific binding to MHC or T cell receptors, the term "modifying" reads on both positive and negative responses and the term "T cell function" reads

on all functions of T cells, including functions that are not T cell specific. Therefore, the claimed functions are not specific enough to sufficiently define the genus of peptides encompassed by the instant claim recitations. Because the functions are not specific, determining which peptides have those functions is unpredictable and would require one of ordinary skill in the art to perform undue experimentation to determine which peptides can be used in the claimed invention.

The specification has not adequately disclosed a condition "characterized by an aberrant, unwanted or otherwise inappropriate immune response." The terms "aberrant," "unwanted" and "inappropriate" are terms that are not sufficiently enabled by the disclosure in the specification. These terms refer to conditions that are defined by subjective human opinion and not objective facts. What is aberrant, unwanted and inappropriate to one may be normal, wanted and appropriate to another. It is not sufficient to define the genus of conditions by opinions, which are subjective and may change over time or which may vary between those of ordinary skill in the art. For the same reasons as recited *supra* with respect to homologs and derivative sequences, the specification has not adequately disclose the genus of conditions characterized by an aberrant, unwanted or otherwise inappropriate immune response to "a functional derivative, homologue, mutant or analogue" of Lol p 5. This recitation encompasses the genus of conditions characterized by immune responses to peptides that have any number of mutations, additions or deletions, so long as they are a "mutant" of Lol p 5 "derived" from Lol p 5, "homologous" over a subsequence to Lol p 5 or "analogous" in structure or function to Lol p 5. The genus of such conditions has not adequately been disclosed in the specification nor has the specification

provided a limiting definition for the term. Therefore, one of ordinary skill in the art would be required to perform undue experimentation to use the recited peptides in the recited function of incubating cells from patients with the genus of such conditions to determine whether T cell function has been modified or whether the peptides have interacted with the T cells in some manner. Also at issue is whether a kit comprising the recited peptides can be used to diagnose or monitor the genus of conditions that the specification has not adequately disclosed. The term "diagnose" implies one to one correspondence between a result and a condition. The specification has not adequately disclosed how the genus of peptides encompassed may be used to diagnose or monitor any particular condition, much less the genus of conditions "characterized by an aberrant, unwanted or otherwise inappropriate immune response." One of ordinary skill in the art would be required to perform undue experimentation to practice the invention commensurate in scope with the claims.

The disclosure in the specification does not provide enablement for the use of any Lol p 5 peptide of 5 or more contiguous amino acids in the instant invention. The specification fails to provide sufficient guidance as to which core structures of the Lol p 5 polypeptides are essential for using the peptides for the recited functions. Absent the ability to predict which of these peptides would function as claimed, and given the lack of data on regions critical for activity, for one of skill in the art to practice the invention as claimed would require a level of experimentation that is excessive and undue.

The art of Zeiler et al. teaches that CD4+ Th cell epitopes of allergens are approximately 10-20 amino acids in length. (PTO-892; Reference W; In particular, page 52, lines 5-8 and page

53, second full paragraph, whole document). Therefore, the specification is not enabled for the use of the genus of isolated T cell epitopes comprising 5 amino acids of Lol p 5 that are capable of interacting with T cells and modifying T cell function when incubated with cells from subjects having a condition characterized by an aberrant, unwanted or otherwise inappropriate immune response to Lol p 5 or a functional derivative, homologue, mutant or analogue. An isolated T cell epitope comprising 5 amino acids of Lol p 5 may have 5-15 amino acids that are unrelated to Lol p 5 and it would be unpredictable as to whether the response elicited by such an epitope would be attributable to the portion that is derived from Lol p 5.

Further, the specification has not adequately disclosed the genus of peptides encompassed by an amino acid sequence derived or selected from the group consisting of: (i) amino acids 37-81; (ii) amino acids 118-137; (iii) amino acids 145-173: (iv) amino acids 172-191; and (v) amino acids 190-245; inclusive of Lol p 5 or a homolog thereof wherein X2 is not the amino acid sequence 100-119 or 190-209 or when the amino acids sequence is 217-236. The specification is not enabled for amino acids "37-81," "118-137," "145-173," "172-191," "190-245,"100-119" "190-209" and "217-236" of Lol p 5 or a derivative or homolog thereof. The recitation of specific amino acid position numbers without reference to a specific sequence is not enabled by the specification's disclosure. The specification does not provide a limiting definition for "Lol p 5" or derivatives and homologs thereof such that one of ordinary skill in the art would recognize how to make and use such a genus of polypeptides. Further, derivatives and homologues of Lol p 5 may reasonably comprise amino acids additions, deletions and/or substitutions that would impact amino acid sequence numbering. Therefore, the recitation of specific amino acids positions within the genus of virtually unlimited "Lol p 5" sequences encompassed is not enabled

by the instant specification. As such, one of ordinary skill in the art would be required to perform undue experimentation to practice the invention commensurate in scope with the claims.

The term "corresponds substantially" in reference to a peptide that corresponds substantially to SEQ ID NO:53 has not adequately been disclosed in the specification. The specification does not have a limiting definition for the term "corresponds substantially" such that one of ordinary skill in the art would be able to make and use the genus of peptides that correspond substantially with SEQ ID NO:53. In addition, the genus of peptide encompassed includes peptides that correspond substantially with a subsequence of SEQ ID NO:53. As discussed supra, the art teaches that that sequence-based methods for function prediction are inadequate and knowing a protein's structure, i.e., amino acid sequence, does not necessary tell one its function and that protein function is context-dependent and the state of the art of making functional assignments merely on the basis of some degree of similarity between sequences and the current structure prediction methods is unreliable. Therefore, determining which peptides of the genus of peptides encompassed by the instant claim recitation that would exhibit the requisite function would be unpredictable.

Also at issue is whether or not the peptide disclosed will have use as a "pharmaceutical composition." In view of the absence of a specific and detailed description in the specification of how to effectively use the genus of peptides encompassed by the instant claims as a pharmaceutical composition, absence of working examples providing evidence which is reasonably predictive that the claimed pharmaceutical composition is effective for in vivo use, and the lack of predictability in the art at the time the invention was made, an undue amount of experimentation would be required to practice the claimed pharmaceutical composition with a

reasonable expectation of success.

Substantiating evidence may be in the form of animal tests, which constitute recognized screening procedures with clear relevance to efficacy in humans. See Ex parte Krepelka, 231 USPQ 746 (Board of Patent Appeals and Interferences 1986) and cases cited therein. Ex parte Maas, 9 USPQ2d 1746.

Reasonable correlation must exist between the scope of the claims and scope of the enablement set forth. In view on the quantity of experimentation necessary the limited working examples, the nature of the invention, the state of the prior art, the unpredictability of the art and the breadth of the claims, it would take undue trials and errors to practice the claimed invention

14. Claims 2, 19, 27, 34, 36-37, 45 and 48 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is in possession of: an Lol p 5 peptide consisting at least 5 contiguous amino acids of SEQ ID NOs 2 or 59-61 and the isolated peptides comprising an Lol p 5 T cell epitope of SEQ ID NOs 33-36, 42, 45-46, 48, and 51-54.

Applicant is not in possession of: an isolated peptide **comprising a Lol p 5 T cell epitope said peptide comprising at least 5 contiguous amino acids** of an amino acid sequence **derived** or selected from the group consisting of: (i) **amino acids 37-81**; (ii) **amino acids 118-**

137; (iii) **amino acids 145-173:** (iv) **amino acids 172-191**; and (v) **amino acids 190-245**; inclusive of **Lol p 5 or a homolog thereof**; and wherein said peptide molecule is capable of interacting with T cells and modifying T cell function when incubated with cells from subjects having a condition characterized by an aberrant, unwanted or otherwise inappropriate immune response to Lol p 5 or **a functional derivative, homologue, mutant or analogue** of said peptide provided that **X2** is not the amino acid sequence **100-119 or 190-209** of claim 2; wherein said amino acid sequence **comprises at least 5 amino acids derived** from amino acid sequences selected from the group consisting of: DVNAGFKAAVAAAANAPPAD (SEQ ID NO:33); ELQIVDKIDAAFKIAATAA (SEQ ID NO:45); DAAFKIAATAANAAPTNDKE (SEQ ID NO:46); PEVKYAVFEAALTKAITAMT (SEQ ID NO:53); and AALTKAITAMTQAQKAGKPA (SEQ ID NO:54) of claim 19; wherein said amino acid sequence is **amino acids 217-236** inclusive of **Lol p 5 or a homolog thereof** of claim 27; wherein said amino acid sequence **corresponds substantially to SEQ ID NO:53** of claim 34; wherein said modification of T cell functioning is the induction of T cell differentiation of claim 36; wherein said **peptide** exhibits reduced or ablated IgE binding of claim 37; a pharmaceutical composition comprising **a peptide according to claim 1 or 2** together with one or more pharmaceutically acceptable carriers and/or diluents of claim 45; and a diagnostic kit for use in diagnosing or monitoring a condition in a mammal, which condition is characterized by an aberrant, unwanted or inappropriate response to Lol p 1 and/or Lol p 5,wherein said kit comprises **a peptide according to claim 2** of claim 48.

Applicant has disclosed only amino acid sequences of Lol p 5 (SEQ ID NO:2); three

isoforms of Lol p 5: Lol p 5A (SEQ ID NO: 59), Lol p 5C (SEQ ID NO:60) and Lol p 5B (SEQ ID NO:61); and the isolated peptides comprising an Lol p 5 T cell epitope of SEQ ID NOs 33-36, 42, 45-46, 48 and 51-54 (In particular, Figures 3-4, whole document); therefore, the skilled artisan cannot envision all the contemplated peptides, pharmaceutical compositions and kits recited in the instant claims. Consequently, conception cannot be achieved until a representative description of the structural and functional properties of the claimed invention has occurred, regardless of the complexity or simplicity of the method. Adequate written description requires more than a mere statement that it is part of the invention. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC1993). The Guidelines for the Examination of Patent Application Under the 35 U.S.C.112, ¶1"Written Description" Requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 20001, see especially page 1106 3rd column).

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath

at page 1116.). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

Applicant is directed to the final Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

16. Claims 2, 19, 27, 34, 36-37 and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Suphioglu et al. (Reference C60; IDS filed on 05/19/2008).

Suphioglu et al. teaches thirty 12-mer and four 13-mer peptides of Lol p 5, including Peptide 28 (consisting of amino acids 218-229 of Lol p 5) dissolved in sterile water (pharmaceutically acceptable carrier or diluent) (In particular, Table 1; Sections 2.4.1-2.4.4 on page 295, whole document). Peptide 28 comprises at least 5 contiguous amino acids of amino acids 190-245 of Lol p 5 and is not amino acid sequence 100-119 or 190-209. Peptide 28 also comprises at least 5 amino acids of instant SEQ ID NO:53, (amino acids 217-236 of Lol p 5). Peptide 28 (218-229 of Lol p 5) "corresponds substantially" to SEQ ID NO:53 (amino acids 217-236 of Lol p 5). Peptide 28 exhibits reduced and ablated IgE binding (In particular, Table 1).

The recitation of "wherein said peptide molecule is capable of interacting with T cells and modifying T cell function when incubated with cells from subjects having a condition characterized by an aberrant, unwanted or otherwise inappropriate immune response to Lol p 5 or a functional derivative, homologue, mutant or analogue or said peptide " in claim 2 and "wherein said modification of T cell functioning is the induction of T cell differentiation" of claim 36 are inherent features of the claimed peptide. While the reference is silent about these functional limitations, the reference peptide is the same as the claimed peptide. Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the referenced sequences. Products of identical chemical composition can not have mutually exclusive

properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01.

Claim 45 is included in this rejection because the reference composition of Peptide 28 in sterile water is compatible with pharmaceutical use as defined in the specification.

The reference teachings anticipate the claimed invention.

16. Claims 2, 19, 27, 34, 36-37, 45 and 48 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 7,112,333 (PTO-892; Reference A).

U.S. Patent 7,112,333 teaches teaches twenty-eight 20-mer and one 19-mer peptides of Lol p 5, including SEQ ID NO:24/LIX-22 peptide (consisting of amino acids 211-230 of Lol p 5) and SEQ ID NO:25/LIX-23 peptide (consisting of amino acids 221-240) comprising a T cell epitope in a pharmaceutically acceptable carrier or diluent) (In particular, Figure 2, column 12, lines 56-58, whole document). SEQ ID NO:24/LIX-22 and SEQ ID NO:25/LIX-23 each comprise at least 5 contiguous amino acids of amino acids 190-245 of Lol p 5 and are not amino acid sequence 100-119 or 190-209. SEQ ID NO:24/LIX-22 and SEQ ID NO:25/LIX-23 also comprises at least 5 amino acids of instant SEQ ID NO:53, (amino acids 217-236 of Lol p 5). SEQ ID NO:24/LIX-22 (211-230 of Lol p 5) and SEQ ID NO:25/LIX-23 (221-240 of Lol p 5) "corresponds substantially" to SEQ ID NO:53 (amino acids 217-236 of Lol p 5). The reference teaches that SEQ ID NO:24/LIX-22 (211-230 of Lol p 5) and SEQ ID NO:25/LIX-23 (221-240

of Lol p 5) exhibit reduced or ablated IgE binding (In particular, Figure 13B). The reference teaches that the peptides may be administered in vivo in a pharmaceutical composition (In particular, column 12, line 50 to column 15, line 54) and that they may be used in reagents (a kit) for diagnosis of allergies (In particular, column 18, lines 9-14).

The recitation of "wherein said peptide molecule is capable of interacting with T cells and modifying T cell function when incubated with cells from subjects having a condition characterized by an aberrant, unwanted or otherwise inappropriate immune response to Lol p 5 or a functional derivative, homologue, mutant or analogue or said peptide " in claim 2; and "wherein said modification of T cell functioning is the induction of T cell differentiation" of claim 36 are inherent features of the claimed peptide. While the reference is silent about these functional limitations for these specific peptides, the reference peptide is the same as the claimed peptide. Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the referenced sequences. Products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01.

The reference teachings anticipate the claimed invention.

17. No claim is allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nora M. Rooney whose telephone number is (571) 272-9937. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

May 11, 2009

Nora M. Rooney

Patent Examiner

Technology Center 1600

/Nora M Rooney/

Examiner, Art Unit 1644